Appl. No. 10/531,855
Amdt. dated November 16, 2010
Reply to Office Action of August 17, 2010

PATENT

REMARKS/ARGUMENTS

Applicants respectfully request entry of the present amendment. Upon entry of the present amendment, claims 1, 4, 7, 13, 16, 20, 25, 26, 28-30, 32 and 33 will be pending in the application. Claims 16 and 25 are amended, claims 8, 9, 19, 22-24, 30 and 31 are canceled, and new claims 32 and 33 are added by the present amendment.

Claim 16 is amended to incorporate former dependent claims 23 and 24. Support for the amendment to claim 16 can be found in the specification at, *e.g.*, paragraph 0038 of the published application (US 2006/0142220 A1). Claim 25 is amended to incorporate former dependent claim 8. Support for the amendment to claim 25 can be found in the specification at, *e.g.*, paragraph 0010 of the published application. Support for new claims 32 and 33 can be found in the specification at, *e.g.*, paragraphs 0011 and 0013, respectively, of the published application. No new matter is added.

Claim Rejections - 35 USC §112

The claims stand rejected under 35 USC §112, first paragraph, because the specification allegedly does not enable the full scope of the claimed invention.

The Examiner states that the specification enables a method for extending blood circulatory half-life of a recombinant human C1 inhibitor by removing or modifying O-linked carbohydrates via *in vitro* modification of Gal(β1-3)GalNAc or Gal(β1-4)GalNAc moieties. *See* p. 2, last paragraph of Office Action (OA). The Examiner further states that the specification does not enable (i) changing the circulatory half-life of any other glycoprotein (*see* paragraph bridging pp. 2-3 of the OA), nor the use of any carbohydrate modifying enzymes other than ST3Gal I and ST3Gal III to increase circulatory half-life of the human C1 inhibitor (*see* p. 4, first paragraph of the OA).

In view of the Examiner's remarks in connection with the enablement rejection, Applicants submit that independent claim 1 (and its dependent claims 4 and 13), as well as dependent claims 7, 8, 9 and 24 are free of the art and enabled by the specification. Each of these claims recites a recombinant human C1 inhibitor, and the method claims each recite the

specific enzymes exemplified in the specification, *i.e.*, ST3Gal I and ST3Gal III for sialylation of carbohydrates comprising Gal(β1-3)GalNAc and Gal(β1-4)GalNAc, and Endo-α-N-Acetylgalactosaminidase for removal of non-sialylated O-linked carbohydrates comprising Gal(β1-3)GalNAc). *See* Examples 2 and 4. Thus, there is no basis in the present OA for rejecting claims 1, 4, 7-9, 13 and 24.
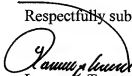
Without agreeing with the Examiner's assertions, Applicants have amended independent claim 16 to incorporate the features of claim 24 (and intervening claim 23), and have amended independent claim 25 to incorporate the features of claim 8. Independent claim 1 has not been amended. Since the present OA provides no basis for the rejection of claims 1, 8 or 24, each of the current independent claims is also free of any outstanding rejection.

Applicants submit that the presently claimed invention is fully enabled by the specification. Modification of the recombinant human C1 inhibitor with each of the recited modification enzymes at carbohydrates comprising the structures recited in the claims is exemplified in the application. *See* Examples 2 and 4. In view of the foregoing, Applicants respectfully request entry of the present amendment and withdrawal of this ground of rejection.

There being no other outstanding rejections, Applicants respectfully request issuance of a Notice of Allowance.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-838-2000.

Respectfully submitted,

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